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| 10/539,100 | 08/10/2005 | Laurence Paris | 2005-222 | 9260 |
| 27569 | 7590 | 01/12/2009 | EXAMINER | |
| PAUL AND PAUL 2000 MARKET STREET SUITE 2900 PHILADELPHIA, PA 19103 | | | | MC GINTY, DOUGLAS J |
| ART UNIT | | PAPER NUMBER | | |
| 1796 | | | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/539,100 | PARIS, LAURENCE | |
| | Examiner | Art Unit | |
| | DOUGLAS MC GINTY | 1796 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 13 November 2008.
 2a) This action is **FINAL**. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 37-62 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 37-62 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on 15 June 2005 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____. | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Status of Prosecution

The claim objections are withdrawn.

The rejection under 35 USC 112, second paragraph, is withdrawn.

The rejection under 35 USC 102(b) over Paris (US 6,331,205) is withdrawn.

The rejection under 35 USC 103(a) over Paris (US 6,331,205) is maintained.

The rejection under 35 USC 103(a) over Paris (US 6,331,205) in view of Scott (WO 01/07507) is maintained.

A new grounds of rejection under 35 USC 112, first paragraph, is made.

Applicable statutes, rules, caselaw, and policies may be found in the previous Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 37-62 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. With respect to claim 37, process steps (a)-(d) do not appear to be fully

supported by the application as originally filed. Compare, pp. 6, 15-17, 20, and 21 of the specification, as well as original claims 32-36.

Double Patenting

Claims 37-62 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 40 of copending Application No. 10/511,260.¹

Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of 10/511,260 also involve a process with a viscous aqueous or hydroalcoholic composition used for manufacturing soft capsules.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented. This rejection may be overcome with a proper Terminal Disclaimer.

Claim Rejections - 35 USC § 103

Claims 37-62 are rejected under 35 U.S.C. 103(a) as obvious over Paris (US 6,331,205).²

Paris teaches a process for manufacturing gelatinized films for soft capsules (Abstract). The reference teaches dissolving at least one thickening agent such as a carrageenan in an aqueous or hydroalcoholic dissolution medium to form a viscous encapsulating mass (col. 2, lines 42-55). A film complexing agent is provided which contains a film complexing agent, and the complexing solution is contacted with the

¹ This application has been published as US 2005/0244489.

² US 6,331,205 issued more than one year before PCT/FR03/03740 was filed. US 6,331,205 also is equivalent to WO99/07347, published 2-18-99.

Art Unit: 1796

viscous encapsulating mass to form a gelled material (col. 2, line 52, through col. 3, line 67). The gelled film is used to make soft capsules (col. 5, lines 44-48).

Paris does not appear to teach the steps of forming an ungelled film from the encapsulating mass or contacting the ungelled film with the complexing solution to "instantly" gel the ungelled film.

Nevertheless, the viscous encapsulating mass would have intrinsically formed a film at the interface of the container wall, and when the complexing agent was added that film would have gelled. The term "instantly" also is a relative term without clear-cut upper and lower limits. Present claim 59 appears to indicate that "instantly" includes a time between 10 seconds and 10 minutes.

It would have been obvious for the process of manufacturing gelatinized film, as taught by Paris, to have the steps of forming an ungelled film followed by contacting that film with a complexing solution to "instantly" form a gel film, because Paris teaches the steps of mixing the ungelled mass and the complexing solution to form a soft capsule. The term "instantly" appears to include times as long as 10 minutes.

With respect to claims 38-62, Paris has the following additional teachings:

Aqueous viscous composition is taught for the manufacture of soft capsules. Abstract.

Gelatization occurs with the addition of thickening agents. Col. 1, line 50, through col. 2, line 10.

Elasticity is controlled with plasticizers. Col. 3, lines 5-15.

Disintegration is controlled with surfactants or polysaccharides. Col. 3, lines 20-67.

Preservation is controlled with preservatives. Col. 4, lines 1-10.

The soft capsules may contain oily and/or aqueous solutions. Col. 4, lines 25-50.

The thickening agents include lambda carrageenans. Col. 2, lines 25 and 26.

The thickening agent is > 5% in the medium. Col. 1, lines 55-60.

The prior art taught using an additional gelling, i.e., thickening agent. Col. 2, lines 40-50.

The amount of thickening agent may be >5% to 80%. Col. 2, lines 45-55.

The amount of alcohol may be between 0 and 60%. Col. 2, lines 48-51.

Solubilization agents include alkali and alkaline earth ions in the amount of 1-50 vol%. Col. 2, line 66, through col. 3, line 10.

The alkaline or alkaline-earth ion is introduced in the form of a hydroxide or a salt of hydrochloric, sulfuric, nitric, phosphoric, or citric acid, and derivatives. Col. 3, lines 1-5.

The pH can vary between 5 and 12. Col. 2, lines 55-60.

Various buffering systems, including the citrate, phosphate, phthalate, and carbonate systems, are taught. Col. 2, lines 50-65.

Plasticizing agents such as glycerol, etc., are taught at col. 3, lines 9-15.

The plasticizing agent may be present in the amount of 0-30 vol%. Col. 3, lines 15-20.

Ionic, nonionic, and amphoteric surfactants are taught at col. 3, lines 25-60.

The amount of surfactant can be 0-20 vol%. Col. 3, lines 60-65.

Starch-type disintegrating agents can be added as well. Col. 3, lines 60-67.

Corn, rice, manioc, wheat starches are taught at col. 3, lines 60-67.

Amounts of 0-20 vol% are taught at col. 3, lines 65-67.

Preservatives and/or coloring adjuvants are taught. Col. 4, lines 1-3.

Preservatives may be present in the amount of 0-10 vol%. Col. 4, lines 1-5.

The coloring agent can be 0.01-5 vol%. Col. 4, lines 5-10.

Opaque agents can be 0-10 vol%. Col. 4, lines 5-10.

Saline solutions, i.e., acid salts, and hydroalcoholic solutions are taught at col. 2, line 66, through col. 3, line 10.

The amount of polyhydric alcohol is 0-60%. Col. 2, lines 48-51.

Salts, hydroxides, carbonates, and alkaline earth ions are taught at col. 2, line 52, through col. 3, line 9

The amount of salts, hydroxides, and carbonates may be 0-50 vol% and the pH can range from 5 to 12. Col. 2, line 55, through col. 3, line 10.

The solution is transferred to the machines for processing, i.e., immersion. Col. 5, lines 40-50.

Lubricants are taught at col. 4, lines 35-26.

The soft capsules may contain oily and/or aqueous solutions. Col. 4, lines 25-50.

Processing steps are taught at col. 5, lines 30-55.

Temperatures of 70-100°C are taught at col. 5, lines 50-55.

The solution is transferred to the machines for processing, i.e., immersion. Col. 5, lines 40-50.

Drying occurs at -4°C. Col. 5, lines 45-50.

Temperatures of 70-100°C are taught at col. 5, lines 50-55.

A vacuum is applied. Col. 5, lines 35-40.

With respect to Claim 54, Paris does not appear to teach the C₁₋₄ alcohols claimed. Nevertheless, the reference teaches polyhydric alcohols (col. 2, lines 48-51) and dissolution agents (col. 4, lines 42-44). Lower MW alcohols such as ethanol would

have been an obvious variation because they are water soluble and have a hydroxy unit. Those lower MW alcohols also would have been well known dissolution agents.

With respect to Claim 59, Paris does not specify a gelatinization time of 10 seconds to 10 minutes. Nevertheless, the reference does teach processing until a viscous mass is formed. Paris, col. 5, lines 30-45. Gelatinization would intrinsically occur within that time period, at the time the viscous mass forms. MPEP 2112 et seq.

Based on the foregoing, claims 37-62 would have been obvious. Overlapping ranges would have been obvious. MPEP 2144.05, I. Obviousness only requires a reasonable expectation of success. *In re O'Farrell*, 853 F.2d 894, 904 (Fed. Cir. 1988); MPEP 2143.02, I. Times and temperatures would have been result-effective variables which would have optimizable through routine experimentation. MPEP 2144.05, II.A.

Claims 37-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Paris as applied to claims 37-62 above, and further in view of Scott (WO 01/07507).

With respect to Claim 38, Paris does not appear to specifically teach thickening agents other than carrageenans.

Nevertheless, Scott teaches that other thickening agents, such as those also presently claimed, could be used in place of carrageenan. Scott, p. 9, line 21, through p. 10, line 23. The reference also teaches the use of viscous aqueous liquids for making soft capsules. Scott, Abstract.

In view of the record as a whole, therefore, it would have been obvious to substitute the carrageenan taught by Paris with the other thickening agents taught by Scott because both references teach viscous aqueous compositions for making soft

capsules and Scott further teaches that other thickening agents would work as well. "The combination of familiar [components] according to known methods is likely to be obvious when it does no more than yield predictable results." *KSR Intern. Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1739 (2007).

Response to Arguments

Applicant's arguments filed November 13, 2008 have been fully considered but they are not persuasive.

The Applicants argue that the "present application relates to the composition of the capsule shell, not the content *per se*." This argument is not persuasive because present claim 62, which depends from present claim 37, also involves the content of the capsule.

The Applicants assert that their claimed invention does not require gelling agents such as gelatin. Still, the present claims have the term "comprising" which does not exclude those gelling agents.

The Applicants urge that the carrageenans in Paris do not function as gelling agents. However, the reference refers to carrageenan as a "gelling agent" in its Abstract.

The Applicants argue that Paris does not teach the steps of (b) forming an ungelled film, (c) providing a complexing solution, and (d) contacting the ungelled film with the complexing solution to "instantly" gel the ungelled film. Nevertheless, as discussed above, those steps would have been obvious.

The Applicants assert that it would not have been obvious to combine the teachings of Paris and Scott. Still, Scott was cited to show that thickeners other than carrageenans were known in the art for use in making soft capsules. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Douglas McGinty whose telephone number is (571) 272-1029. The examiner can normally be reached on M, W, Th, F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Seidleck can be reached on (571) 272-1078. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Douglas McGinty/
Primary Examiner
Art Unit 1796